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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,514	04/26/2007	Eiichi Momotani	1349.46042X00	4749

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EXAMINER	
SWARTZ, RODNEY P	
ART UNIT	**PAPER NUMBER**
1645	

MAIL DATE	DELIVERY MODE
10/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,514	MOMOTANI ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' Response to Office Action, received 2 July 2008, is acknowledged. Claims 1-3 have been amended. New claims 4-6 have been added.

2. Claims 1-6 are pending and under consideration.

Rejections Withdrawn

3. The objection to Figures 2, 3, 4, and 5 is withdrawn in light of the submission of replacement drawings.

4. The rejection of claims 1 and 2 under 35 U.S.C. 112, first paragraph, scope of enablement for the use of other single antigens from *M. avium* subsp. *paratuberculosis*, is withdrawn in light of the amendment of the claims.

Rejections Maintained

5. The rejection of claims 1-3 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, is maintained.

Applicants argue that the amendment of the claims obviates the rejection.

The examiner has considered applicants' arguments in light of the amendments, but does not find them persuasive. Although the amendments do obviate some of the original rejection, the question of distinguishing between infected and noninfected subjects remains. Page 10, lines 3-15, states that measuring the amount of produced IFNγ is the step of discriminating between infected and noninfected animals, not just detecting any amount of produced IFNγ. Thus, the claims remain missing an essential step, i.e., comparison of detected amounts of produced IFNγ from normal animals with that detected in animals suspected of infection, with a particular level higher than normal as indicative of infection.

6. The rejection of claim 3 under 35 U.S.C. 112, first paragraph, scope of enablement for methods of diagnosis of any/all other mycobacterial diseases and infections using only a single antigen from any/all mycobacteria, is maintained.

Applicants argue that the amendment of the claim obviates the rejection, in light of the submitted references.

The examiner has considered applicants' arguments in light of the amendments, but does not find them persuasive. The original rejection explanation is concerned with the claimed invention that one can diagnose any mycobacterial disease or mycobacterial infection, regardless of which species is responsible, by utilizing any other species or antigens from any other species of mycobacteria. The specification does not teach such cross-reactivity between species. The submitted references do not teach universal cross-reactivity between species of mycobacteria for production of IFNγ in *in vitro* or *in vivo* tests.

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Newly added claims 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

The omitted steps are: 1) comparison of results with control values, and; 2) determination of cutoff value which determines a positive infection.

The specification teaches that even uninfected cattle show some level of interferon gamma production (Page 10, lines 3-15; Figures 1-7) and that measuring the amount of produced IFNγ is the step of discriminating between infected and noninfected animals, not just detecting any amount of produced IFNγ. Thus, the claims omit an essential step, i.e., comparison of detected amounts of produced IFNγ from normal animals with that detected in animals suspected of infection, with a particular level higher than normal as indicative of infection.

9. Newly added 6 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for distinguishing between *M. avium* subsp. *paratuberculosis* infected and uninfected cattle by using *M. avium* subsp. *paratuberculosis* PPD, does not reasonably provide enablement for methods of diagnosis of any/all species of mycobacterial diseases and infections utilizing an antigen(s) from any/all other species mycobacteria. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of

experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention - a method for diagnosing any/all species of mycobacterial diseases or infections comprising adding anti-IL10 antibody and an antigen from any/all other species of *Mycobacterium* to blood and measuring an amount of interferon-γ after culture.

The state of the prior art as evidenced by the instant specification indicates that the specific assay utilizing PPD from *M. avium* subsp. *paratuberculosis* has not been performed prior to the instant application. Koets et al (*Vet. Immunol. Immunopathol.*, 70(1-2):105-115, 1999) teach that substituting a single antigen for PPD from *M. avium* subsp. *paratuberculosis* does not result in the same reactivity utilizing samples from cattle infected with *M. avium* subsp. *paratuberculosis.* Thus, there is a lack of predictability in the art that merely substituting PPD from *M. avium* subsp. *paratuberculosis* with any single antigen from *M. avium* subsp. *paratuberculosis* would result in the ability to diagnosis infection by *M. avium* subsp. *paratuberculosis* utilizing the instant methodology.

In addition, the state of the prior art as evidenced by Cole (2002), Lind (1984) and Merkal (1984) shows that antigens of all of the species of *Mycobacterium* do not always share immunological crossreactivity.

The amount of direction or guidance present is insufficient for the broad scope of the instant claims, i.e., any antigen isolated from any species of *Mycobacterium* can be utilized in the instant methods for diagnosis of any/all other species of mycobacterial disease or infections inventions because the specification utilizes only PPD from *M. avium* subsp. *paratuberculosis* or concanavalin A to diagnosis infection with *M. avium* subsp. *paratuberculosis*.

Thus, the quantity of experimentation necessary to determine if any single antigen (or even combinations of single antigens) from *M. avium* subsp. *paratuberculosis* can substitute for the PPD actually utilized constitutes merely an invitation to experiment without a reasonable expectation of success.

Conclusion

10. All claims are finally rejected.

11. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

October 10, 2008

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/572,514	MOMOTANI ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	